PATENT
Atty. Docket No.: 8576.0068

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,795,864)
)
Issued: August 18, 1998)
)
To: Gary Arthur Amstutz, Stephen Scott Bowersox,)
Kishorchandra Gohil, Peter Isadore Adriaenssens,)
Ramasharma Kristipati)
)
Assignee: ELAN Pharmaceuticals, Inc.)
)
For: STABLE OMEGA CONOPETIDE FORMULATIONS)

ATTN: MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICATION FOR EXTENSION OF PATENT
TERM UNDER 35 U.S.C. § 156

Applicant, ELAN Pharmaceuticals, Inc., represents that it is the Assignee of the entire interest in and to United States Patent No. 5,795,864 granted to Gary Arthur Amstutz, Stephen Scott Bowersox, Kishorchandra Gohil, Peter Isadore Adriaenssens and Ramasharma Kristipati on the 18th day of August, 1998, for Stable Omega Conopetide Formulations by virtue of an assignment from the inventors to Neurex Corporation, recorded in the U.S. Patent and Trademark Office at Reel 7575, Frame 0234 on June 27, 1995, and from Neurex Corporation to ELAN Pharmaceuticals, Inc. recorded at Reel 9689, Frame 0776 on January 4, 1999. By the Power of Attorney enclosed herein (Attachment A), Applicant appoints several individual attorneys, including Charles E. Van Horn, as attorneys for ELAN Pharmaceuticals, Inc. with regard

to this application for extension of the term of U.S. Patent No. 5,795,864 and to transact all business in the U.S. Patent and Trademark Office in connection therewith.

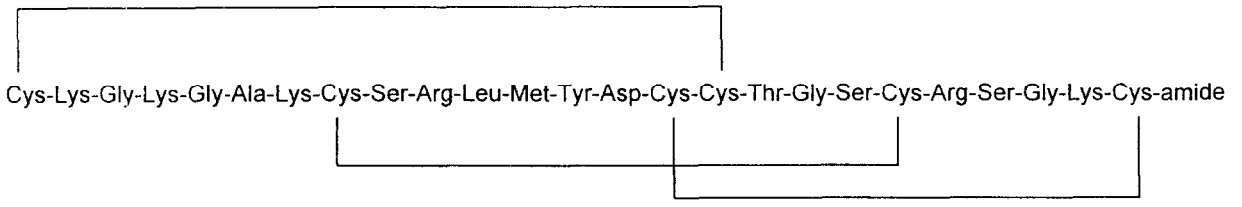
Notice Regarding Multiple Applications

Applicant has filed another application for term extension (U.S. Patent No. 5,364,842) based on the regulatory review period for the product PRIALT®. Applicant will make an election of only one patent in accordance with 37 C.F.R. § 1.785(b) upon receipt of a notice of final determination in these applications from the Patent and Trademark Office.

Information Required Under 37 C.F.R. § 1.740

Applicant hereby submits this application for extension of the patent term under 35 U.S.C. § 156 by providing the following information required by the rules promulgated by the U.S. Patent and Trademark Office (37 C.F.R. § 1.740). For the convenience of the Patent and Trademark Office, the information contained in this application will be presented in a format which follows the requirements of Section 1.740 of Title 37 of the Code of Federal Regulations.

(1) The approved product PRIALT® contains ziconotide, a synthetic equivalent of a naturally occurring conopeptide found in the piscivorous marine snail, *Conus magus*. Ziconotide is a 25 amino acid, polybasic peptide containing three disulfide bridges with a molecular weight of 2639 daltons and a molecular formula of $C_{102}H_{172}N_{36}O_{32}S_7$. The amino acid sequence and disulfide bridging pattern are given below:



PRIALT® is formulated as a sterile, preservative-free, isotonic solution that contains ziconotide acetate with L-methionine and sodium chloride as excipients.

(2) The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act Section 505.

(3) The approved product PRIALT® received permission for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act on December 28, 2004. A copy of the approval letter for NDA 21-060 is attached (Attachment B).

(4) The active ingredient in PRIALT® is ziconotide which, on information and belief, has not been approved for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act prior to the approval of NDA 21-060 by the Food and Drug Administration on December 28, 2004. A copy of the package insert describing the approved product is attached (Attachment C).

(5) This application for extension of patent term under 35 U.S.C. § 156 is being submitted within the permitted 60-day period pursuant to 37 C.F.R. § 1.720(f), said period will expire on February 25, 2005.

(6) The complete identification of the patent for which a term extension is being sought is as follows:

Inventors: Gary Arthur Amstutz, Stephen Scott Bowersox, Kishorchandra Gohil, Peter Isadore Adriaenssens, Ramasharma Kristipati

Patent No.: 5,795,864

Filing Date: June 27, 1995

Issue Date: August 18, 1998

Expiration Date: June 27, 2015

(7) A true copy of the patent is attached (Attachment D).

(8) No reexamination certificate or certificate of correction has been issued on this patent. A copy of a record of maintenance fee payments under 35 U.S.C. § 41(b) is attached (Attachment E).

(9) U.S. Patent No. 5,795,864 claims a formulation comprising the active ingredient ziconotide (an omega conopeptide) in PRIALT®. The applicable patent claims are claims 1, 2 and 4 that are directed to a formulation that contains the active ingredient. The following description demonstrates the manner in which at least one claim reads on the approved product.

Claim 1 reads as follows: A stable omega conopeptide formulation comprising an omega conopeptide and an anti-oxidant composition capable of preventing methionine oxidation.

Ziconotide, the active ingredient in PRIALT®, is an omega conopeptide. Ziconotide is described, for example, as SEQ ID NO:1 (MVIIA/SNX-111) at col. 3, line 17 of the '864 patent. PRIALT® contains L-methionine as an anti-oxidant.

(10) The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

Investigational New Drug Application (IND 45718) for PRIALT® was received by the FDA on July 5, 1994 and became effective on August 4, 1994.

New Drug Application for PRIALT® (NDA 21-060) was submitted on December 28, 1999.

New Drug Application for PRIALT® was approved on December 28, 2004.

(11) A brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to PRIALT® and the dates applicable to these significant activities are set forth in a chronology of events in Attachment F.

(12)(i) Applicant is of the opinion that U.S. Patent No. 5,795,864 is eligible for extension of the patent term under 35 U.S.C. § 156 because it satisfies all requirements for such extension as follows:

(a) 35 U.S.C. § 156(a) - U.S. Patent No. 5,795,864 claims a formulation containing the active ingredient (an omega conopeptide) in PRIALT®.

(b) 35 U.S.C. § 156(a)(1) - U.S. Patent No. 5,795,864 has not expired before submission of this application.

(c) 35 U.S.C. § 156(a)(2) - The term of U.S. Patent No. 5,795,864 has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3) - The application for patent term extension is submitted by the owner of record of the patent in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. § 156(d) and the rules of the Patent and Trademark Office.

(e) 35 U.S.C. § 156(a)(4) - The product PRIALT® has been subjected to a regulatory review period before its commercial marketing or use.

(f) 35 U.S.C. § 156(a)(5)(A) - The commercial marketing or use of the product PRIALT® after the regulatory review period is the first permitted commercial marketing or use under the provision of the Federal Food, Drug and Cosmetic Act (i.e., Section 505) under which such regulatory review period occurred.

(g) 35 U.S.C. § 156(c)(4) - No other patent has been extended for the same regulatory review period for the product PRIALT®.

(12)(ii) Applicant respectfully submits that the length of the extension of patent term for U.S. Patent No. 5,795,864 is 3.36 years (1228 days) pursuant to 35 U.S.C. § 156(c). The length of the extension was determined pursuant to 37 C.F.R. § 1.775 as follows:

(a) The regulatory review period under 35 U.S.C. § 156(g)(1)(B) began on August 4, 1994 and ended December 28, 2004, which is a total of 3801 days, which is the sum of (1) and (2) below:

(1) The period of review under 35 U.S.C. § 156(g)(1)(B)(i), the "Testing Period," began on August 4, 1994 and ended on December 28, 1999, which is 1973 days; and

(2) The period of review under 35 U.S.C. § 156(g)(1)(B)(ii), the "Approval Period," began on December 28, 1999, and ended on December 28, 2004, which is a total of 1828 days.

(b) The regulatory review period upon which the period of extension is calculated is the entire regulatory review period as determined in subparagraph 12(ii)(a) above (3801) less:

(1) The number of days in the regulatory review period which were on or before the date on which the patent issued (August 18, 1998) which is 1475 days; and

(2) The number of days during which applicant did not act with due diligence, which is zero (0) days; and

(3) One-half the number of days determined in subparagraph (12)(ii)(a)(1) above after the patent issued (one-half of 498) which is 249 days;

(c) The number of days as determined in subparagraph (12)(ii)(b) (2077 days) when added to the original term of the patent (June 27, 2015) would result in the date of March 4, 2021.

(d) Fourteen (14) years when added to the date of the NDA approval (December 28, 2004) would result in the date of December 28, 2018;

(e) The earlier date as determined in subparagraphs (12)(ii)(c) and (12)(ii)(d) is December 28, 2018;

(f) Since U.S. Patent No. 5,795,864 issued after September 24, 1984, the period of extension may not exceed five years from the original expiration date of June 27, 2015. Five years when added to the original expiration date of the patent would result in the date of June 27, 2020.

(g) The earlier date as determined by subparagraphs (12)(ii)(e) and (12)(ii)(f) is December 28, 2018.

(13) Applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) The prescribed fee for receiving and acting upon this application is attached as a check in the amount of $1,120.00. The Director is authorized to charge any additional fees required by this application to Deposit Account No. 06-0916.

(15) All correspondence and inquiries may be directed to the undersigned, whose address, telephone number and fax number are as follows:

Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
Phone: 202-408-4072
Fax: 202-408-4400

(16) Enclosed is a certification that the application for extension of patent term under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and two (2) copies thereof (Attachment G).

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Charles E. Van Horn
Charles E. Van Horn
Reg. No. 40,266

Date: February 22, 2005

Attachments:
Power of Attorney (Attachment A)
Approval Letter (Attachment B)
Package Insert for PRIALT® (Attachment C)
U.S. Patent No. 5,795,864 (Attachment D)
Maintenance Fees Paid (Attachment E)
Chronology of Regulatory Review Period (Attachment F)
Certification of Copies of Application Papers (Attachment G)